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Stephen A. Slusher, Reg. No. 43,924

4 November, 2002
(Date)

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Applicants: Bernt Sweder VAN ASBECK
and Johannes Josephus Maria MARX

Serial No.: 09/700,669

Examiner: KETTER, James S.

Priority claimed to PCT/NL99/00316

Filed: 16 November 2000

Group Art Unit: 1636

**For: USE OF A NUCLEIC ACID-BINDING
CHEMOTHERAPEUTIC AGENT, AND
A PHARMACEUTICAL COMPOSITION**

Commissioner for Patents
Washington, D.C. 20231

Sir:

Provisional Election. In response to the Office Communication mailed October 2, 2002, the Applicants provisionally elect the claims of Group I, and respectfully traverses the restriction requirement and request that it be reconsidered.

The Examiner asserts the existence of two inventions: Group I, with claims 7-10, asserted to be drawn to a method of treating viral infection with a chemotherapeutic agent, e.g., bleomycin or adriamycin; and Group II, with claims 11-13, asserted to be drawn to a pharmaceutical comprising a therapeutic agent, e.g., bleomycin or adriamycin. Applicant provisionally elects the claims of Group I.

Grounds for Traverse. The Examiner's requirement for restriction between claims 7-10 (Group I) and claims 11-13 (Group II) is respectfully traversed.

The Examiner cites PCT Rules 13.1 and 13.2, and argues that the inventions of Groups I and II do not relate to a single general inventive concept because "they lack the same or corresponding special technical features for the following reasons: the special technical feature is drawn to chemotherapeutic agents known in the art, e.g., bleomycin or adriamycin, as recited."

Under PCT Rule 13.2, the "expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." As is clear from the PCT Rules and Annex B, Administrative Instructions Under the PCT (part of the MPEP; citations are to the August 2001 edition), the issue is whether there is a "single general inventive concept." The examples given in Annex B, Part 1, paragraph (e) (i) make it clear that "[t]he method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application: (i) in addition to an independent claim for a given product . . . an independent claim for a use of the said product . . ." Thus a claim to a product (here Group II) and a claim for a use of the product (here Group I) form a single general inventive concept, so long as there is the same or a corresponding "special technical feature" in common among the claims. *One "special technical feature" is the same for both groups.*

The Office Action appears to posit that because the specified agents are "known in the art" they cannot constitute a special technical feature. There is no authority for this proposition in the PCT Rules or Administrative Instructions of which Applicant is aware. The sole question is related to patentability: i.e., do the technical features define contributions which each of the inventions (here Groups I and II), considered as a whole, make over the prior art? In this context, this clearly refers to methods and pharmaceutical preparations for treating diseases caused by virions by administration of a nucleic acid-binding chemotherapeutic agent that complexes a metal ion. That the chemotherapy agent, such as

bleomycin or adriamycin, may be known does not give rise to a lack of unity of invention, particularly where as here the claims are presumptively patentable over the prior art.

The International Preliminary Examination Report in this case (dated 22 August, 2000) establishes that original claims 1 to 6 are novel, involve an inventive step, and have industrial applicability. Present claims 7 to 13 are parallel to original claims 1 to 6, and are simply restated in the preferred United States formats (e.g., omitting "characterized by" language). There is no suggestion of record that claims 7 to 13 are not patentable over the prior art.

The claims of Group I are drawn to a method of treatment of virion disease, which method includes administration of a defined chemotherapeutic agent. The claims of Group II are drawn to a pharmaceutical preparation, which preparation includes the defined chemotherapeutic agent, complexed to a metal ion, and further including an iron chelating compound. The commonality between the two is clear -- the common technical feature is the defined chemotherapeutic agent, particularly for treatment of virion disease. That the International Preliminary Examination Report establishes patentability makes clear that this is a contribution "over the prior art" within the meaning of Rule 13.2.

That Group II includes, for example, a metal ion and an iron chelating compound does not change the analysis. While addition of one or both of these constituents may contribute to patentability of the pharmaceutical preparation claim of Group II, nonetheless the special technical feature defining the invention is clearly the chemotherapeutic agent.

Yet another reason for withdrawal of the restriction requirement is that as a practical matter, it is submitted very little additional effort and time would be required in examining all claims on the merits; particularly given that the prior art developed by searching the method claims will also be applicable to the product claims. An international search has been conducted, and an International Preliminary Search Report established.

Applicants respectfully request that the restriction requirement be reconsidered and withdrawn, and that all the claims of the Application proceed to an examination upon the merits. Should

the Examiner have any comments, questions or suggestions relating to a speedy disposition of the application, he is invited to call the undersigned at (505) 998-6130.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Stephen A. Slusher', written over a horizontal line.

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